

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, *et al.*,

Plaintiffs and Relator,

v.

NPC PHARMACEUTICALS
CORPORATION,

Defendant.

11 Civ. 0071 (PGG)

UNITED STATES OF AMERICA,

Plaintiff,

v.

NPC PHARMACEUTICALS
CORPORATION,

Defendant.

THE UNITED STATES OF AMERICA’S TRIAL MEMORANDUM OF LAW

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Pursuant to Section X.B.2 of the Court's Individual Practices and Procedures, plaintiff the United States of America (the "United States" or "Government") submits this trial memorandum of law addressing issues of law that the Government expects to arise at or before trial.¹

PRELIMINARY STATEMENT

The Government intends to prove at trial that defendant Novartis Pharmaceutical Corporation ("NPC" or "Novartis") violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), by paying hundreds of millions of dollars of kickbacks to doctors in the form of speaker honoraria, lavish dinners, and entertainment, for the purpose of inducing those doctors to prescribe NPC drugs, and thereby caused the submission of hundreds of millions of dollars in false reimbursement claims for NPC drugs to federal health insurance programs, in violation of the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA").

The Government anticipates that the Court will need to address a number of key legal issues before or during the trial. First among these issues is the standard of causation. NPC asserts that the Government must prove that (1) the bribes NPC provided to doctors caused those doctors to prescribe more NPC drugs than they otherwise would have absent the bribes; (2) doctors entered into *quid pro quo* agreements with NPC to prescribe its drugs; and (3) doctors accepted the bribes knowingly and willfully. *See* Joint Request to Charge, Defendant's Proposed Instructions D-2, D-3, D-7, D-8 D-9, D-13. Courts, however, in this jurisdiction and elsewhere, have uniformly rejected such arguments as contrary to the FCA. Instead, courts have held that the Government need only prove that NPC provided kickbacks to doctors in violation of the

¹ Plaintiffs the State of New York and Oswald Bilotta also join in the trial memorandum of law.

AKS, that those doctors later prescribed NPC drugs, and that reimbursement claims for those drugs were then submitted to federal healthcare programs.

Second, the Court will need to address the baseless argument that to prove that NPC provided remuneration to doctors under the AKS, the Government must show that the honoraria NPC provided to doctors exceeded the fair market value for speaker services. *See* Joint Request to Charge, Defendant's Proposed Instructions D-4, D-5, D-11. Apart from the fact that this proposed standard ignores all of the other benefits NPC conferred to doctors in the form of expensive meals, trips, and entertainment, it has no discernable applicability to the facts in this case. The Government has never alleged that NPC gave kickbacks to doctors by overpaying them for otherwise legitimate speaking services. Rather, the Government's position has always been that NPC bribed doctors by paying them cash for sham speaker events.

Third, the Court should reject NPC's claim that it may be held liable only for the conduct of employees "with authority," presumably managers or senior executives. *Id.* Defendant's Proposed Instruction A-11, D-15. NPC is wrong. Courts have long held corporate defendants liable under the FCA for the conduct of all employees acting within the scope of their employment.

Fourth, NPC's proposed jury instructions seek to impose an intent requirement that is contrary to the plain terms of the AKS. Specifically, NPC asserts that Plaintiffs must prove that NPC "intended a Government Health Care Program to pay for the prescriptions written in exchange for unlawful remuneration." Joint Request to Charge, Defendant's Proposed Instruction D-13. The AKS does not impose such a requirement, however. All that is required is that NPC is aware that payment "*may be made* in whole or in part under a Federal health care program." 42 U.S.C § 1320a-7b(b)(2) (emphasis added).

ARGUMENT

I. TO ESTABLISH LIABILITY, THE GOVERNMENT NEED NOT PROVE THAT DOCTORS CHANGED THEIR PRESCRIPTION WRITING BEHAVIOR IN RESPONSE TO NPC KICKBACKS, THAT DOCTORS HAD *QUID PRO QUO* ARRANGEMENTS WITH NPC, OR THAT DOCTORS VIOLATED THE AKS

To establish liability, the Government need only show that (1) NPC paid kickbacks to doctors to induce them to prescribe the drugs at issue, (2) the doctors thereafter prescribed those drugs, and (3) claims for payment for those prescriptions were submitted to a federal health care program. *See U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96-100 (3d Cir. 2018) (Government need only show a link—not “but for” causation—between the individual or entity receiving a kickback and the submission of a claim for reimbursement to a federal health care program); *U.S. ex rel. Bawduniak v. Biogen Indec, Inc.*, No. 12-cv-10601-IT, 2018 WL 1996829, at *3, *6 (D. Mass. Apr. 27, 2018) (finding sufficient allegations that “Defendant paid kickbacks to [specific] physicians . . . to induce those physicians to prescribe particular medications, and that the physicians then prescribed those medications, causing claims to be submitted to Medicare and Medicaid”); *see generally U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (“In order to avoid FCA liability . . . [,] a participant in a federal health care program [must] refrain from offering or entering into payment arrangements which violate the AKS, while making claims for payment to the Government under that program.”).

NPC contends that the Government must prove that the remuneration NPC provided to physicians caused those physicians to write prescriptions for NPC drugs that they otherwise would not have written, that the physicians had a *quid pro quo* arrangement with NPC to prescribe NPC drugs, and that the physicians knowingly and willingly accepted the bribes. Joint Request to Charge, Defendant’s Proposed Instructions D-2, D-3, D-7, D-8 D-9, D-13. These

arguments ignore the above-cited cases, as well as the intent of Congress underlying both the AKS and FCA.

The Government alleges that NPC is liable under the FCA for causing claims to be submitted that were “false” because they were tainted by the kickbacks it allegedly paid to doctors, in violation of the AKS. The AKS ensures that doctors’ decision-making is based solely on the medical needs of their patients, and is not potentially affected by financial considerations. *U.S. v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). By making the payment or receipt of kickbacks a felony, *see* 42 U.S.C. § 1320a-7b(b), the AKS ensures that the Government pays only for medical care that is conflict-free and provided in the best interests of patients. A kickback eliminates that assurance because it taints the kickback-recipient’s medical decisions with financial interest. In other words, the kickback creates the very real possibility that the recipient’s medical decisions were not based entirely on his or her independent medical judgment, but (in whole or in part) on the kickback. As a result, “[t]he Government does not get what it bargained for” when it pays for items or services “tainted by a kickback,” *Greenfield*, 880 F.3d at 97 (quoting *Wilkins*, 659 F.3d at 314), as “[k]ickbacks are designed to influence providers’ independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole,” *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53 (D. Mass. 2011).

Accordingly, courts have concluded that claims for medical care that are tainted by a violation of the AKS are “false” under the FCA, and that the kickback provider is liable for any such claims submitted for reimbursement to the Government. *See, e.g., Wilkins*, 659 F.3d at 313; *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011); *U.S. ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259-60 (11th Cir. 2005); *U.S. ex rel.*

Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004); *see also Westmoreland*, 812 F. Supp. 2d at 54-55 (collecting cases).

The claims are false because compliance with the AKS is material to the Government's payment decision; the Government does not get what it bargained for when a doctor's independence is potentially compromised by a kickback. *See id.* Thus, once it has been established that a claim tainted by a kickback has been submitted to the Government, it is irrelevant to the liability analysis whether the doctor who received the kickback would have written the same prescriptions even absent the kickback. *See Greenfield*, 880 F.3d at 96-100 (plaintiff need not "prove a kickback actually influenced a patient's or medical professional's judgment"); *Bawduniak*, 2018 WL 1996829, at *3, *6 (liability can be established "regardless of whether the claim was the result of a *quid-pro-quo* exchange or would have been submitted even absent the kickback"). Indeed, as another district court in this District previously held, "'the AKS does not require a kick-back scheme to succeed in generating new business (*i.e.*, new patient prescriptions) in order for a violation to have occurred.'" *U.S. ex rel. Arnstein v. Teva Pharms. USA, Inc.*, No. 13-cv-3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) (quoting *U.S. ex rel. Kester v. Novartis Pharms. Corp.*, 23 F. Supp. 3d 242, 263 (S.D.N.Y. 2014)).

For the same reason, whether NPC entered into an explicit *quid pro quo* agreement with any doctor to prescribe NPC drugs is immaterial. *See, e.g., Hanlester Network v. Shalala*, 51 F.3d 1390, 1397 (9th Cir. 1995) ("reject[ing] the proposition that proof of an agreement is necessary under [subsection (b)(1) or (b)(2) of the AKS]"); *U.S. ex rel. Pasqua v. Kan-Di-Ki LLC*, No. 10-965-JST, 2012 WL 12895229, at *4 (C.D. Cal. June 18, 2012) ("Proof of an agreement to refer business is not necessary to establish an AKS violation.").

Accordingly, to establish liability for its FCA claims here, the Government need not show that the doctors who allegedly received kickbacks from NPC changed their prescription-writing habits after receiving the kickbacks, or that NPC and the doctors entered into a *quid pro quo* arrangement to do so. Instead, as set forth above, the Government need only show that NPC paid kickbacks to doctors, and those doctors thereafter wrote prescriptions for the drugs at issue for which a claim was submitted to a federal health care program. *See Greenfield*, 880 F.3d at 96-100; *Bawduniak*, 2018 WL 1996829, at *3, *6. While the Government must identify a link between the alleged kickbacks and the false claims, the requisite link is established by showing that a doctor who received a kickback thereafter wrote prescriptions for the relevant drugs for which a claim was submitted to a federal health care program, *see Greenfield*, 880 F.3d at 99-100.

Greenfield is instructive here. It involved allegations that Accredo, a specialty pharmacy, paid kickbacks to two charities, “HSI” and “HANJ,” to induce the charities to refer their members to Accredo. *Id.* at 91-92. To survive summary judgment, the Third Circuit held that the relator had to “point to at least one claim [submitted to a federal health care program] that covered a patient who was recommended or referred to Accredo by HSI/HANJ.” *Id.* at 99. The relator did not, however, have to show that the patient would not have been recommended or referred to Accredo absent the kickbacks or that the kickbacks otherwise played a role in the recommendation or referral. *See id.* at 99-100. Similarly, here, the Government must show that a doctor who received a kickback thereafter wrote a prescription for one of the NPC drugs at issue for which a claim was submitted to a federal health care program, but they need not show that the kickback actually affected the doctor’s prescribing decision.

The recent ruling of Chief Judge Colleen McMahon in *Teva*, another *qui tam* action involving alleged kickbacks to doctors through speaker programs, is directly on point. In *Teva*, as here, the defendant drug manufacturer argued on summary judgment that to prevail, relators must prove that a *quid pro quo* arrangement or that a kickback caused a doctor to write additional prescriptions. *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, 13 Civ. 3702 (CM), at *23-27 (S.D.N.Y. Feb. 27, 2019). Chief Judge McMahon rejected this argument, holding that plaintiffs need only show that the pharmaceutical company provided a kickback to a doctor and that the doctor subsequently wrote one or more prescriptions for that company's drugs. *Id.* As the Chief Judge explained:

Relators need not show that a *quid pro quo* exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.

Id. at *24 (quoting *U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018)). The Court should reach the same conclusion here.

NPC reliance on the Second Circuit's summary affirmance of a jury instruction in a criminal AKS case in *United States v. Krikheli*, 461 F. App'x 7 (2d Cir. 2012) (cited in Joint Request to Charge, Defendant's Proposed Instruction D-8, D-9, D-13), is misplaced. The instruction that the Second Circuit affirmed in *Krikheli* did not require the Government to prove that there was a *quid pro quo* arrangement, only that the defendants intended that there be one. In the section of the jury charge defining the requisite intent standard, the district court instructed the jury that the prosecution had to prove that: (1) "one purpose of the offer or payment [at issue] was to induce a person to refer patients to another"; (2) "[t]o induce a person means to attempt to gain influence over the reason or judgment of that person"; and (3) "the remuneration

was offered or paid as a quid pro quo in return for the referring of the patient. *Id.* at 11 (emphasis added). The defendants argued on appeal that the district court should have instructed the jury as well that the payments had to be made to a person who could make referral decisions, as opposed to a middleman. The Second Circuit rejected this argument, concluding that “the instructions made clear that the government was required to prove that any payments to middlemen *were made to induce* referrals in a *quid pro quo* transaction.” *Id.* (emphasis added). Thus, the Second Circuit affirmed a jury instruction that required the prosecution to prove that the defendants intended the payments as an inducement to get referrals. Accordingly, *Krikheli* supports the Government’s position that it need not prove that NPC’s bribes actually caused doctors to prescribe or that there was a *quid pro quo* agreement, only that NPC intended to induce doctors to prescribe its drugs.

Finally, contrary to NPC’s assertions, the Government need not prove that doctors knowingly and willfully accepted bribes. While subsection (b)(1) of the AKS permits the Government to pursue those (like the doctors here) who “solicit[] or receive[]” kickbacks, 42 U.S.C. § 1320-7b(b)(1), the Government has not sued any individual doctors. The Government has sued NPC and thus the operative AKS provision here is subsection (b)(2), which addresses those (like NPC here) who “offer[] or pay[]” kickbacks, *id.* §1320-7b(b)(2). NPC’s payment of such kickbacks itself constituted a violation of the AKS under subsection (b)(2), regardless of whether the doctors’ acceptance of the kickbacks constituted a separate violation the AKS under subsection (b)(1). Accordingly, to establish liability on the part of NPC, the Government need not show that any particular doctor violated the AKS.

II. TO ESTABLISH LIABILITY, THE GOVERNMENT NEED NOT SHOW THAT THE REMUNERATION THAT NPC PROVIDED TO DOCTORS EXCEEDED THE FAIR MARKET VALUE FOR SERVICES RENDERED

NPC proposes to instruct the jury that “payments equal to or less than the fair market value for services rendered under written contracts, such as honoraria payments to doctors, are not considered a kickback or a bribe”; that “[i]n order to establish that any honorarium payment to a speaker meets the ‘remuneration’ element of the AKS, Plaintiffs must show that the payment exceeded ‘fair market value’; and that “[t]o do so, Plaintiffs must identify a reliable benchmark for what fair market value is and show that the payment exceeded that benchmark.” *See* Joint Request to Charge, Defendant’s Proposed Instructions D-4, D-5, D-11. Yet, none of these instructions is applicable here, as fair market value of honoraria is not at issue.

While the AKS does define the term “remuneration” broadly to include, among other benefits, “transfers of items or services for free or for other than fair market value,” 42 U.S.C. § 1320a–7a(i)(6), this trial will not be about the fair market value of legitimate speaker services. The Government does not contend that NPC’s kickbacks to doctors took the form of above fair market value honoraria for otherwise legitimate speaker services. Rather, the Government claims that the speaker and roundtable events were shams and that NPC was simply providing cash and extravagant meals to doctors to induce them to prescribe Novartis drugs. Thus, while the fact that NPC paid doctors exorbitant sums for bogus speaker events is certainly important evidence of NPC’s bribery scheme, the Government is not required to prove that NPC paid speakers honoraria for speaker events that exceeded fair market value.

The cases NPC cites to support its view that proof of above fair market value payments is required are plainly inapposite. The Government need not distinguish *U.S. ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1054 (C.D. Cal. 2016), because the court in that case did so itself. In *Brown*, the relator alleged that the speaker honoraria Celgene paid to doctors was an

inducement to prescribe Celgene drugs, Celgene presented undisputed evidence on summary judgment that speaker selection had nothing to do with prescription writing and that speakers were paid fair market value, and there was no evidence that the events were shams or otherwise used as a means to induce speakers to prescribe Celgene drugs. In granting summary judgment, the court explicitly distinguished *Brown* from the facts in this case, noting for example that there was “no evidence that speeches were given at unconventional venues or in the absence of bona fide attendees.” *Id.* at 1055. Thus, the court granted summary judgment not because the relator failed to prove above fair market value honoraria, but because there was no evidence that the speaker events were a pretext to pay bribes.

Equally unhelpful to NPC is *Bingham v. BayCare Health Sys.*, No. 8:14-CV-73-T-23JSS, 2016 WL 8739056 at *6 (M.D. Fla. Dec. 16, 2016). Fair market value was actually a key issue in *Bingham* because the alleged kickback took the form of below market rent charged by a hospital to a medical practice for office space and parking. Nothing of that sort is at play here, as the Government does not assert that NPC paid doctors above market for bona fide speaker events.

The other cases NPC cites similarly involve fair market value only because, unlike here, the alleged bribe took the form of an overpayment or an undercharge. *See United States ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683 (N.D. Miss. 2012) (government alleged that durable medical equipment supplier violated the AKS by offering as remuneration contract billing services priced below fair market value); *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622 (N.D. Ill. 2006) (relator alleged that hospitals paid kickbacks to ambulance companies for patient referrals by paying above market rates); *United States ex rel. Perales v. St. Margaret’s Hosp.*, 243 F. Supp. 2d 843, 851 (C.D. Ill. 2003) (hospital’s otherwise legitimate purchase of

medical practice was not a kickback to the seller absent evidence that price hospital paid was above fair market value).

If fair market value of honoraria were relevant, and it is not, NPC would have the burden of proving it. To the extent that NPC contends that paying fair market value qualifies NPC for protection under the regulatory safe harbor for personal services and management contracts, *see* 42 C.F.R. § 1001.952(d), “safe harbors are affirmative defenses, and the defendant carries the burden of proof at trial.” *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa 2014) (citing *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D.Ill.2006)). “To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute.” *Id.* (internal quotations and citation omitted). Among other things, NPC would have to prove that the aggregate amount paid to each doctor “is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.” 42 C.F.R. § 1001.952(d)(5). In any event, safe harbor protection will not be available to NPC if the Government proves at trial that one of NPC’s purposes in paying doctors honoraria was to induce them to prescribe NPC drugs. *See Bartlett*, 39 F. Supp. 3d at 677 (“Importantly, under the Anti-Kickback Statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).” (quoting OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005))).

III. NPC IS LIABLE FOR THE CONDUCT OF ALL EMPLOYEES WHO ACTED WITHIN THE SCOPE OF THEIR EMPLOYMENT

NPC contends that it cannot be held liable unless the Government proves that an employee “with authority” knowingly and willfully violated the AKS. Joint Request to Charge, Defendant’s Proposed Instructions A-11, D-15. To the extent that NPC is arguing that an NPC manager or senior executive must have perpetrated, directed, or known of the kickbacks NPC employees provided to doctors, that position has no basis in law.

It is well established that employers may be held liable under the FCA for the conduct of their employees within the scope of their employment. *See U.S. ex rel. Jones v. Brigham and Women’s Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir. 2012) (“We have long held that corporate defendants may be subject to FCA liability when the alleged misrepresentations are made while the employee is acting within the scope of his or her employment.”); *U.S. ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402 (3d Cir. 1999) (same); *United States v. Hangar One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977) (same); *United States v. Pierre Bouchet*, 1987 WL 11565 at *6 (S.D.N.Y. May 21, 1987) (granting summary judgment to the Government on FCA claim based on knowledge of fraud by corporate defendant’s book-keeper); *United States v. Inc. Village of Island Park*, 888 F. Supp. 419, 437-39 (E.D.N.Y. 1995) (granting summary judgment to the Government on FCA claim based on awareness of fraud by clerk). Courts impute to corporate employers the knowledge of fraud by their employees because the employees gained such knowledge in the scope of employment. *See U.S. v. Anchor Mortg. Corp.*, 711 F.3d 745, 747-48 (7th Cir. 2013) (“Corporations . . . ‘know’ what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do something about that knowledge.”).

Fraud committed by employees acting within the scope of their employment will be imputed to the corporate employer regardless of whether a manager or senior executive directed or was even was aware of the employee's conduct. *See e.g., Grand Union Co. v. United States*, 696 F.2d 888, 890-91 (11th Cir. 1983) (knowledge of food stamp fraud by low-level employees – “check-out cashiers” at a supermarket chain – “can be imputed to [defendant]” under the FCA even though there was no evidence of knowledge by “the head cashier.”); *United States v. Associates in Eye Care, P.S.C.*, No. 13-27-GFVT, 2014 WL 414231, at *8 (E.D. Ky. Feb. 4, 2014) (“courts have found employers vicariously liable under the FCA for acts of employees when the employees acted within the scope of their employment” and “the government does not necessarily need to allege that [the corporate employer] endorsed or directed [the employee's] behavior for vicarious liability to attach”); *U.S. ex rel. Bryant v. Williams Building Corp.*, 158 F. Supp. 2d 1001, 1008 (D.S.D. 2001) (“[T]he majority of cases . . . hold a principal liable whenever its agent acts within the scope of employment or with apparent authority, regardless of the principal's knowledge, culpability, policies, or efforts to restrain the employee's bad acts.”).

As courts have recognized, imputing to corporate defendants their employees' knowledge of fraud when such knowledge is gained in the scope of employment aligns with well-established principles of vicarious liability. Specifically, the court in *Village of Island Park* based its decision to impute knowledge of the village clerk to the municipal corporation employing him on long-standing tenets of tort and agency law. *See* 888 F. Supp. at 437 (adopting definitions of actual and apparent authority from *Prosser on Torts* and Restatement (Second) of Agency). Similarly, in *Williams Building*, the court concluded that holding the corporate defendant vicariously liable for the knowledge of its employee accords with basic principles of agency. 158 F. Supp. 3d at 1008 (relying on the Supreme Court's application of agency principles to

impute knowledge of corporate employees to their employer in *A.S.M.E. v. Hydrolevel Corp.*, 456 U.S. 556, 566 (1982)).

The “scope of employment” test for imputing knowledge of fraud to corporate defendants also accords with the core remedial and deterrent purposes of the FCA. *See U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943) (the FCA’s “chief purpose was to provide for restitution to the government of money taken from it by fraud”); *Rainwater*, 356 U.S. at 592 (“objective of Congress [in enacting the FCA] was broadly to protect the funds and property of the government”); *O’Connell*, 890 F.2d at 568 (one of the FCA’s purposes is “to deter fraud against the government”). More specifically, as the First Circuit recognized, “both of these goals are served by” applying tort principles of “vicarious liability” to FCA claims against corporations. *O’Connell*, 890 F.2d at 568. Further, legislative history makes plain that, when it amended the FCA to expand the definition of “knowingly” in 1986, Congress was well aware of the risks of fraud against the public fisc by corporate defendants and intended for the FCA to be “a more effective weapon against Government fraud.” S. Rep. No. 99-345, at 4; *see also id.* at 7 (1986) (expansion of FCA’s *scienter* definition intended to prevent “ostrich-like conduct” by “corporate officers [designed to] insulate themselves from knowledge of false claims”). Thus, the Court should adopt the “scope of employment” standard in this case

NPC also seeks a jury instruction that prohibits the Government from showing corporate liability “by piecing together scraps of innocent knowledge from different corporate officials and employees who never had contact with each other or did not know what others were doing in connection with remuneration paid to a doctor.” But, such an instruction, based on *United States v. Science Applications Intern. Corp.*, 626 F.3d 1257 (D.C. Cir. 2010), would be wholly inappropriate here. This is not a case like *Science Applications*, where there was no evidence that any one employee knew the corporation caused false claims to be submitted and the

Government sought to prove corporate scienter by combining the collective knowledge of multiple employees. In this case, by contrast, the Government will present evidence that numerous NPC employees acting within the scope of their employment knowingly and willfully provided kickbacks to doctors and thereby knowingly caused false claims to be submitted to federal health care programs for NPC drugs that these doctors later wrote. Accordingly, there is no need to instruct the jury on collective knowledge, which would only create confusion.

IV. TO ESTABLISH LIABILITY, THE GOVERNMENT NEED ONLY PROVE THAT NPC INTENDED THAT DOCTORS IT BRIBED WOULD PRESCRIBE NPC DRUGS FOR WHICH PAYMENT MAY BE MADE BY GOVERNMENT HEALTHCARE PROGRAMS

NPC contends that “because AKS liability is limited to prescriptions reimbursed by Plaintiff health care programs, not private parties, to satisfy their burden Plaintiffs must prove by a preponderance of the evidence that Novartis and doctors intended a Government Health Care Program to pay for the prescriptions written in exchange for unlawful remuneration.” Joint Request to Charge, Defendant’s Proposed Instruction D-13. This argument has no merit.

NPC’s proposed standard is squarely contradicted by the unambiguous language of the AKS itself, which states that it prohibits the “knowing[] and willful[] offer[ing] or pay[ing] [of] any remuneration . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment *may be made* in whole or in part under a Federal health care program.” 42 U.S.C § 1320a–7b(b)(2) (emphasis added). Thus, the statute makes clear that to violate the AKS, the Government need only prove that NPC intended that the doctors it bribed would prescribe NPC drugs for which payment *may be made* by a federal healthcare program. If the statute stated that payment *will be made* by a federal healthcare program, Novartis would have a colorable argument that defendants must intend for a federal healthcare program to pay for the item or service that is the goal of the bribe. But, the use of the

word “may” indicates that Congress intended for the AKS to cover not only scenarios in which the defendant specifically intends for a federal healthcare program to pay for the item or service that is the goal of the bribe, but also those in which the defendant knows that a federal healthcare program could pay.

Consistent with the plain terms of the AKS, courts have held that defendants need only know that a Government healthcare program may pay for the item or service to violate the AKS. *See United States v. Miles*, 360 F.3d 472, 480 (5th Cir. 2004) (“In order to obtain a conviction under this statute, the Government must show that a defendant: (1) knowingly and willfully made a payment or offer of payment, (2) as an inducement to the payee, (3) to refer an individual, (4) to another for the furnishing of an item or service that *could be* paid for by a federal health care program.” (emphasis added)); *MedPricer.com, Inc. v. Becton, Dixon and Co.*, 240 F. Supp. 3d 263, 271 (D. Conn. 2017).²

Finally, as to NPC’s suggestion that the Government must prove that doctors intended for Government healthcare programs to pay for the Novartis drugs they prescribed after receiving a bribe, this misstates the law, *see United States, ex rel., Bidani v. Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003) (“The AKS criminalizes receiving remuneration intended to affect decisions to purchase supplies for which payment may be made under Medicare.”). In addition, as discussed

² Novartis’s reliance on *United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 322 n.12 (5th Cir. 2017), is misplaced. In *King*, the Fifth Circuit affirmed summary judgment for the defendant where, unlike here, the relator failed to come forward with any evidence that the defendant bribed anyone. While the court further observed that the relator also failed to show that the defendant intended that a federal healthcare program would pay, such a standard would contradict the plain language of the AKS stating that the item or service that is the goal of the bribe “may be paid” by a federal healthcare program. Notably, such a standard would also be inconsistent with the Fifth Circuit’s prior holding in *Miles*.

above, the Government is not required to prove any doctor's intent because the Government has not sued any doctors.

CONCLUSION

For the foregoing reasons, the Court should rule for the Government on the issues of law described above.

Dated: New York, New York
April 8, 2019

Respectfully submitted,

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